Message

From: Faeth, Lisa [Faeth.Lisa@epa.gov]
Sent: 6/14/2019 2:50:41 PM
To: Anderson, Steve [Anderson.Steve@epa.gov]; Askinazi, Valerie [Askinazi.Valerie@epa.gov]; Baptist, Erik [Baptist.Erik@epa.gov]; Barkas, Jessica [barkas.jessica@epa.gov]; Beck, Nancy [Beck.Nancy@epa.gov]; Bertrand, Charlotte [Bertrand.Charlotte@epa.gov]; Blair, Susanna [Blair.Susanna@epa.gov]; Buster, Pamela [Buster.Pamela@epa.gov]; Canavan, Sheila [Canavan.Sheila@epa.gov]; Caraballo, Mario [Caraballo.Mario@epa.gov]; Carroll, Megan [Carroll.Megan@epa.gov]; Cherepy, Andrea [Cherepy.Andrea@epa.gov]; Christian, Myrta [Christian.Myrta@epa.gov]; Corado, Ana [Corado.Ana@epa.gov]; Davies, Clive [Davies.Clive@epa.gov]; Dekleva, Lynn [dekleva.lynn@epa.gov]; Devito, Steve [Devito.Steve@epa.gov]; Doa, Maria [Doa.Maria@epa.gov]; Drewes, Scott [Drewes.Scott@epa.gov]; Dunn, Alexandra [dunn.alexandra@epa.gov]; Dunton, Cheryl [Dunton.Cheryl@epa.gov]; Edelstein, Rebecca [Edelstein.Rebecca@epa.gov]; Edmonds, Marc [Edmonds.Marc@epa.gov]; Elwood, Holly [Elwood.Holly@epa.gov]; Fan, Shirley [Fan.Shirley@epa.gov]; Farquharson, Chenise [Farquharson.Chenise@epa.gov]; Fehrenbacher, Cathy [Fehrenbacher.Cathy@epa.gov]; Feustel, Ingrid [feustel.ingrid@epa.gov]; Frank, Donald [Frank.Donald@epa.gov]; Gibson, Hugh [Gibson.Hugh@epa.gov]; Gimlin, Peter [Gimlin.Peter@epa.gov]; Gorder, Chris [Gorder.Chris@epa.gov]; Gordon, Brittney [Gordon.Brittney@epa.gov]; Grant, Brian [Grant.Brian@epa.gov]; Gray, Shawna [Gray.Shawna@epa.gov]; Groeneveld, Thomas [Groeneveld.Thomas@epa.gov]; Guthrie, Christina [Guthrie.Christina@epa.gov]; Hanley, Mary [Hanley.Mary@epa.gov]; Helfgott, Daniel [Helfgott.Daniel@epa.gov]; Henry, Tala [Henry.Tala@epa.gov]; Kapust, Edna [Kapust.Edna@epa.gov]; Kemme, Sara [kemme.sara@epa.gov]; Koch, Erin [Koch.Erin@epa.gov]; Krasnic, Toni [krasnic.toni@epa.gov]; Lavoie, Emma [Lavoie.Emma@epa.gov]; Lee, Mari [Lee.Mari@epa.gov]; Lee, Virginia [Lee.Virginia@epa.gov]; Leopard, Matthew (OEI) [Leopard.Matthew@epa.gov]; Liva, Aakruti [Liva.Aakruti@epa.gov]; Lobar, Bryan [Lobar.Bryan@epa.gov]; Menasche, Claudia [Menasche.Claudia@epa.gov]; Morris, Jeff [Morris.Jeff@epa.gov]; Moss, Kenneth [Moss.Kenneth@epa.gov]; Mottley, Tanya [Mottley.Tanya@epa.gov]; Moyer, Adam [moyer.adam@epa.gov]; Myers, Irina [Myers.Irina@epa.gov]; Myrick, Pamela [Myrick.Pamela@epa.gov]; Nazef, Laura [Nazef.Laura@epa.gov]; Ortiz, Julia [Ortiz.Julia@epa.gov]; Owen, Elise [Owen.Elise@epa.gov]; Parsons, Doug [Parsons.Douglas@epa.gov]; Passe, Loraine [Passe.Loraine@epa.gov]; Pierce, Alison [Pierce.Alison@epa.gov]; Pratt, Johnk [Pratt.Johnk@epa.gov]; Price, Michelle [Price.Michelle@epa.gov]; Reese, Recie [Reese.Recie@epa.gov]; Reisman, Larry [Reisman.Larry@epa.gov]; Rice, Cody [Rice.Cody@epa.gov]; Richardson, Vickie [Richardson.Vickie@epa.gov]; Ross, Philip [Ross.Philip@epa.gov]; Sadowsky, Don [Sadowsky.Don@epa.gov]; Santacroce, Jeffrey [Santacroce.Jeffrey@epa.gov]; Saxton, Dion [Saxton.Dion@epa.gov]; Scarano, Louis [Scarano.Louis@epa.gov]; Scheifele, Hans [Scheifele.Hans@epa.gov]; Schmit, Ryan [schmit.ryan@epa.gov]; Schweer, Greg [Schweer.Greg@epa.gov]; Scott Selken [spselken@up.com]; Scott, Elizabeth [Scott.Elizabeth@epa.gov]; Selby-Mohamadu, Yvette [Selby-Mohamadu.Yvette@epa.gov]; Seltzer, Mark [Seltzer.Mark@epa.gov]; Sheehan, Eileen [Sheehan.Eileen@epa.gov]; Sherlock, Scott [Sherlock.Scott@epa.gov]; Simons, Andrew [Simons.Andrew@epa.gov]; Sirmons, Chandler [Sirmons.Chandler@epa.gov]; Slotnick, Sue [Slotnick.Sue@epa.gov]; Smith, David G. [Smith.DavidG@epa.gov]; Smith-Seam, Rhoda [smith-seam.rhoda@epa.gov]; Stedeford, Todd [Stedeford.Todd@epa.gov]; Stevens, Katherine [stevens.katherine@epa.gov]; Strauss, Linda [Strauss.Linda@epa.gov]; Symmes, Brian [Symmes.Brian@epa.gov]; Tanner, Barbara [Tanner.Barbara@epa.gov]; Thompson, Tony [Thompson.Tony@epa.gov]; Tierney, Meghan [Tierney.Meghan@epa.gov]; Tillman, Thomas [Tillman.Thomas@epa.gov]; Tomassoni, Guy [Tomassoni.Guy@epa.gov]; Tran, Chi [Tran.Chi@epa.gov]; Turk, David [Turk.David@epa.gov]; Vendinello, Lynn [Vendinello.Lynn@epa.gov]; Wallace, Ryan [Wallace.Ryan@epa.gov]; Wheeler, Cindy [Wheeler.Cindy@epa.gov]; Widawsky, David [Widawsky.David@epa.gov]; Williams, Aresia [Williams.Aresia@epa.gov]; Williams, Bridget [Williams.Bridget@epa.gov]; Williamson, Tracy [Williamson.Tracy@epa.gov]; Wills, Jennifer [Wills.Jennifer@epa.gov]; Wise, Louise [Wise.Louise@epa.gov]; Wolf, Joel [Wolf.Joel@epa.gov]; Wright, Tracy [Wright.Tracy@epa.gov]; Yowell, John [yowell.john@epa.gov]
Subject: News Articles (For EPA Distribution Only)

BNA DAILY ENVIRONMENT REPORT ARTICLES

EU Could Extend Endocrine Disrupter Controls to Toys, Cosmetics

By Stephen Gardner

Posted June 13, 2019, 1:05 PM

Chemicals that interfere with the hormone system could be restricted in a wider range of products such as toys and cosmetics in the European Union, according to a consultation document issued by the European Commission, the bloc's executive arm.

CHEMICAL WATCH ARTICLES

US EPA round-up

13 June 2019 / Green chemistry, Substance notification & inventories, TSCA, United States

Green chemistry award winners

The US EPA has announced the four awardees of its 2019 Green Chemistry Challenge. The programme honours green chemistry technologies that "turn potential environmental challenges into business opportunities, spurring innovation and economic development".

The winners – which include both individuals and research institutes – are:

- Professor Sanjoy Banerjee, for creating large-scale zinc-manganese oxide batteries that can be recharged thousands of times;
- Kalion, Inc (in partnership with the Massachusetts Institute of Technology), for commercialising the first microbial fermentation process to produce glucaric acid;
- Merck Research Laboratories, for redesigning manufacturing of the antibiotic ZerbaxaTM; and
- WSI, for developing TRUpathTM technology, an alternative to traditional laundering technologies.

The American Chemical Society Green Chemistry Institute judged the contest and made the recommendations to the EPA.

TSCA 'not likely' findings

The EPA has issued TSCA 5(a)(3)(c) findings for three substances subject to pre-manufacture notices (PMNs). These "not likely to present an unreasonable risk" determinations will allow the substances to come to market without restriction.

The determinations cover:

- P-18-0120 – specific: 1H-pyrrole-2,5-dione, 1,1'-C36-alkylenebis-, an adhesive component;
- P-18-0220 – generic: heteromonocycle [(alkylalkylidene)bis(substituted carbomoncycle)]bis-, polymer with alkyl isocyanate, alkenoate (ester), imported in solution and process for use as a UV-curable coating resin; and
- P-18-0339 – generic: alkyl heteromonocycle with heteroatom substituted alkyl cycloalkane and 2-hydroxyethyl heteromonocycle methacrylate-blocked homopolymer, imported for use as an immobilising agent for the microbial promoter of nitrogen decomposition.

The decisions came on 20 and 21 May.

Formal publication of 'not likely' findings

The agency has published statements of findings in the *Federal Register* for new substance applications submitted under section 5(a) of TSCA. Issued in three parts, they cover 'not likely to pose an unreasonable risk' determinations, made between October 2018 and March of this year.

Publication of the statements is required under the reformed law.

Accidental chemical releases named enforcement priority

The EPA has named among its 2020-23 enforcement and compliance priorities reducing the risk of accidental releases at industrial and chemical facilities.

A 12 June statement outlining the seven compliance goals says the agency "has found that many regulated facilities are neither managing adequately the risks they pose nor ensuring the safety of their facilities to protect surrounding communities as required under Clean Air Act". It plans to focus on reducing risk to human health and the environment by making chemical accidents less likely.

Also among the agency's priorities is a goal of reducing childhood lead exposures.

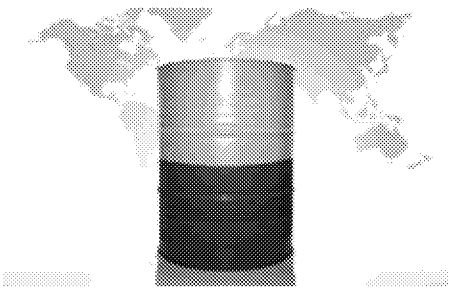
Further Information:

- Green chemistry awards
- TSCA determinations
- October TSCA findings
- Nov-Dec TSCA findings
- Jan-March TSCA findings
- 2020-23 enforcement priorities

Colombia to be informally assessed for OECD mutual data assurance scheme

Programme removes need for duplicate testing

13 June 2019 / Colombia, Data, Latin America & Caribbean



Colombia is being informally assessed this year on whether it meets the qualifications for the OECD's scheme for mutual acceptance of data (MAD).

The country is working on fulfilling the legal requirements in order to comply with the organisation's standards for laboratory practices, according to Mar Gonzalez, senior policy analyst at the OECD.

Ms Gonzalez said that representatives from Mexico, which is a full member of the data assurance scheme, are working with Colombia this year to assess the country's programme for monitoring laboratories. Mexico will report to the next meeting of the OECD's Good Laboratory Practices working group in February 2020 whether the country should be formally evaluated for membership.

Tests carried out in a MAD country laboratory are accepted in all the other countries that are members of the scheme. Colombia joined the OECD last year, which means it is obliged to accept tests carried out in other member countries. But before its monitoring system is evaluated and green-lighted by the OECD's working group, tests carried out in its laboratories aren't automatically accepted in other countries.

The MAD scheme removes the need for duplicate testing for products which are marketed in several countries that accept MAD-approved testing and provides a "common basis for co-operation among national authorities and avoids creating non-tariff barriers to trade", according to the OECD's website.

Increased interest

A "growing number of countries" in Latin America "have expressed an interest in GLP and MAD," according to the OECD's progress report on chemical safety published in April.

In February, a workshop was held in Bogota with around 180 participants from governments and industry in various countries in the region. The workshop covered the basic elements of the GLP and MAD system and how they work in practice, what steps countries could take if they wish to pursue adherence, and the benefits of doing so.

"We're trying to strengthen our relationships with the region, and with the organisations in the region," Ms Gonzalez said.

This increased interest in the OECD's data assurance scheme is part of a broader trend of Latin American countries moving to adopt and upgrade chemical regulation regimes. This is driven in some countries by a desire to join the OECD, and in others from obligations resulting from OECD membership. The organisation requires members to adhere to its policies, some of which relate to chemical management.

Argentina and Brazil are both full members of the MAD scheme, despite not being OECD members. Costa Rica, which is also not an OECD member, is working on fulfilling the legal requirements for MAD membership, Ms Gonzalez said.

Ginger Hervey

UN/emerging markets reporter

Further Information:

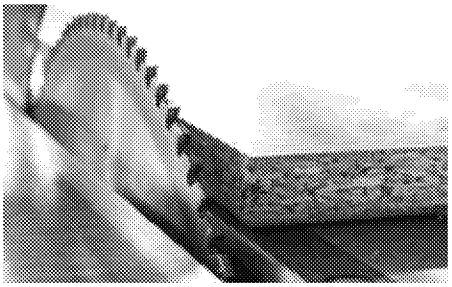
- List of MAD members

- OECD progress report

EU trade groups call for changes to formaldehyde restriction proposal

Test methods source of concern

13 June 2019 / Built environment, CMRs, Europe, REACH



EU trade groups have provided input into the scope of Echa's proposed restriction on formaldehyde, particularly on the most appropriate test methods to measure emissions of the substance.

The agency's proposal would limit formaldehyde, released from consumer articles marketed or used in the EU, to 0.124mg/m^3. Echa says the substance is a highly reactive, acutely toxic gas and a genotoxic carcinogen, making the proposal "effective, practicable and proportionate".

The substance is mainly used as a chemical intermediate to manufacture formaldehyde-based resins and other chemicals. The proposal presents risk management options for "all consumer articles", but identifies the main sources as wood-based panels and articles made from them, such as furniture. Wood-based panels use the resins as bonding agents for wood particles.

Comments

The following trade associations, among others, submitted comments to a public consultation on the proposal:

- the European Furniture Industries Confederation (Efic);
- the European Confederation of Construction Chemicals (EFCC); and
- the European Carpet and Rug Association (ECRA).

They made recommendations on its scope, exemptions and the most appropriate test methods to ensure compliance.

Echa's proposal highlights two EU test methods that measure formaldehyde emissions:

- EN 717-1– this test method is specifically designed to measure formaldehyde from wood-based panels; and
- EN 16516 – this measures emissions of volatile organic compounds, including formaldehyde, from construction products.

Under the restriction, the agency recommends using EN 717-1 because it is "considered more robust for the determination of formaldehyde emissions" and is "deemed more suitable for ensuring compliance".

However, opinion is mixed on whether this is the best option, depending on the articles produced. The EFCC, for example, says EN 717-1 is not suitable for construction chemical products, which are generally mixtures of substances used in the construction sector,. These include additives for cement or sealing and bonding products.

The EFCC suggests the use of EN 16516, as it covers all construction products. ECRA adds that limiting formaldehyde testing to EN 717-1 would make it necessary to test floor coverings and other construction products in two different instances. This would "increase the costs dramatically", it says.

Efic, meanwhile, supports EN 717-1 because it has "proved to be the most reliable, affordable and widely used way to correctly assess formaldehyde emissions".

But it is also concerned that the proposal will create unnecessary obligations for producers. They would, it says, be required to "test not just the panels, but all finished furniture articles".

"As millions of different articles are placed on the market, testing each and every one of them would result in disproportionate costs for the furniture industries," it says. This would be particularly problematic because of insufficient testing facilities, it adds.

The EFCC says formaldehyde emissions from construction products, including construction chemicals, is covered by the EU's Construction Products Regulation (CPR) which requires declarations of performance (DoP) to meet EU member state regulations.

It adds that any potential formaldehyde emissions from construction chemicals products are "significantly lower" than the proposed emission limit value of 0.124 mg/m^3. Therefore, a restriction under REACH for construction chemicals products would be an "unnecessary regulatory overlap".

"Just confirming such a well-known case by requiring double testing would result in useless efforts and additional waste of resources," says the EFCC. It calls for construction chemicals products to either be exempt from the restriction, or that it should be applied under the CPR.

Efic also raises concerns with different limits across member states, as well as various EU regulations. It calls for one mandatory EU limit for formaldehyde emissions, which would reduce costs and simplify procedures for SMEs and prevent the import of non-compliant products in the EU market.

The deadline for comments on the restriction proposal is 20 September.

Leigh Stringer

Global Business Editor

Related Articles

- Echa round-up

Further Information:

- Echa restriction report

- Restriction summary

Decision on REACH authorisation refusal published

13 June 2019 / Alternatives assessment & substitution, Europe, REACH, SVHCs

The European Commission has published a summary of its Decision to reject an application for an authorised use of sodium dichromate because it was not in conformity.

The summary, recently published in the EU's Official Journal, said the application by Hapoc to use the substance in a molten bath form for the treatment of certain micro-surgery medical instruments did not include the necessary information specified in Article 62(4)(d) of REACH.

Related Articles

- REACH authorisation application rejected in EU first

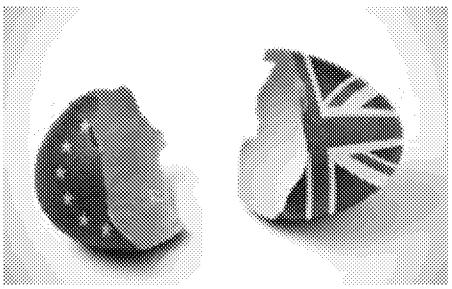
Further Information:

- EU Official Journal

NGO threatens to sue UK government over reduced post-Brexit oversight

Amendments to REACH SI needed to replicate the relevant provisions of EU law

13 June 2019 / Brexit, REACH, UK



UK NGO CHEM Trust is threatening to take the British government to court over "shocking" post-Brexit plans it has put in place that the organisation says reduces oversight of its processes for regulating chemicals.

In a 'pre-action protocol' letter sent on 4 June to environment minister Michael Gove, CHEM Trust says it will be "forced to consider" making an application to the high court of England and Wales for a judicial review unless the government amends the REACH statutory instrument to replicate the relevant provisions of EU law.

The letter, written by law firm Leigh Day on the NGO's behalf, calls for a response by 18 June. It follows another letter sent in April, to which Mr Gove responded a month later.

It says that REACH SI substantially alters the way in which chemicals will be regulated after Brexit, and that no provision is in place for the UK to continue to participate in the current regulatory regime overseen by Echa.

The government has faced strong criticism from MPs and NGOs that the UK legislation mirroring REACH has "stripped out" all committees and associated stakeholder engagement that underpin authorisation and restriction decisions in the EU.

The legislation will only be implemented if the UK breaks free from the bloc without a deal. Currently it is set to leave on 31 October, and MPs are still hoping to get a deal agreed that would allow alignment with REACH and associate membership of Echa.

The CHEM Trust letter says the SI weakens oversight of the designated UK agency – the Health and Safety Executive (HSE) – replacing it with an obligation to simply obtain external scientific advice, and "seriously undermining" the opportunities for public participation.

"This is not an effective way of ensuring well informed and well-balanced decision making," it says.

It challenges the government on five points:

- removal of experience, expertise and participation; and transfer of powers to the Secretary of State;
- removal of due regard for societal needs in decision-making;
- omission of Echa committees and stakeholder engagement in HSE;
- restricting HSE to relying purely on scientific knowledge it has commissioned for its own purposes. This creates significant public risk; and
- lack of arrangements for data-sharing.

Data transfer has been a particular sore point for UK-based REACH registrants due to a requirement for full data sets to be submitted within two years.

It is unclear how UK companies or the HSE will be able to obtain this data, the letter says, also expressing concern over how and whether the UK agency will have the capacity and expertise to process registrations and authorisations.

EDC restriction

The letter also targets the UK's leniency toward endocrine disrupting chemicals in pesticides.

The SI for plant protection products, it says, erases a crucial paragraph from EU law on EDCs, and by doing so permits the approval of substances that could cause harm to humans, non-target organisms and the environment.

"This represents a significant deregulation under the cover of a Brexit process," it says.

The government has acted unlawfully by weakening both REACH and PPP laws, the letter adds. The European Union (Withdrawal) Act, implemented last year, does not allow substantive changes to EU laws when these are transferred into UK law.

The changes also run contrary to "a green Brexit" Mr Gove has promised, it says.

HSE's director of EU exit – chemicals Dave Bench in March responded to criticisms on reduced oversight, saying there is no need to replicate Echa's committees post Brexit as Britain has "some of the best" chemical experts in the world. In a 'no-deal' scenario, he said, mechanisms would be put in place to enable public scrutiny of UK decisions.

Clelia Oziel

Europe correspondent

Related Articles

- UK publishes amended draft REACH SI
- No need for UK to replicate Echa committees post Brexit – HSE
- CBA survey 'confirms' UK REACH data fears
- No-deal Brexit: UK may diverge from EU REACH decisions

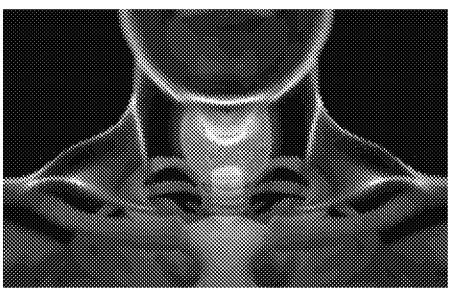
Further Information:

- Letter

Efsa opts not to change TTC guidance for EDCs

Updated guidance following public consultation

13 June 2019 / EDCs, Europe, Food & drink, Risk assessment



The European Food Safety Authority (Efsa) has rejected calls to make changes relating to endocrine-disrupting chemicals (EDCs) in its guidance on using a threshold of toxicological concern (TTC) approach.

The authority published the draft of its *Guidance on the use of the threshold of toxicological concern approach in food safety assessment* last year.

The report on the public consultation, published this month, shows several comments contain calls for changes relating to EDCs. However, the final version of the guidance document does not include those changes.

According to the guidance, the TTC approach can only be used when:

- a substance's chemical structure is known;

- there is limited chemical specific toxicity data; and
- it's possible to estimate exposure.

The guidance lists cases where the TTC approach is never applicable, including assessment of substances with "special properties", such as high-potency carcinogens, steroids, and substances with a potential to bioaccumulate, such as polyhalogenated dibenzodioxins, dibenzofurans and biphenyls.

The Institute of Environmental Medicine at the Karolinska Institute in Sweden suggested that endocrine-active substances should also be routinely excluded from the TTC approach because they may pose "potentially serious risks" to human health at very low doses.

Meanwhile, the German Federal Institute for Risk Assessment (BfR) suggested that Efsa should include specific guidance on using the TTC approach for substances with endocrine-mediated toxicity.

Efsa responded that "if it is known that a substance has endocrine activity and the mode of action is known, then such data should be used and not the TTC approach". No change to the guidance was needed, it added.

The authority directs respondents to a 2012 TTC opinion by its scientific committee, which recommended that decisions on whether to apply the TTC approach should be made on a case-by-case basis if data suggest that substances have endocrine activity, but the relevance to humans is unclear. "If there are data showing that a substance has endocrine-mediated adverse effects, then ... the risk assessment should be based on the data." it said.

In general, the 2012 scientific committee recommended that "untested substances, other than steroids, can be evaluated using the TTC approach".

In updating the guidance, Efsa agreed to a suggestion from The European Crop Protection Association (ECPA) to change "genotoxic substance" to "DNA reactive". ECPA commented that DNA reactive substances have a potential to directly cause DNA damage when present at low levels but "DNA-non-reactive" genotoxicants tend to have threshold mechanisms and "usually do not pose carcinogenic risk in humans at low levels".

The updated guidance highlights a need for "improved" tools to predict bioaccumulation and to assess aggregate exposure to chemicals from multiple sources.

Efsa also recommends a review of existing cancer databases through an "international collaboration effort" and the creation of a non-cancer database.

Dr Emma Davies

Reporter

Related Articles

- Efsa/WHO report gives green light to TTC approach

Further Information:

- Efsa guidance and comments
- Efsa 2012 Opinion

Echa round-up

13 June 2019 / CLP Regulation, Europe, REACH

CLH proposals and intentions

Echa has received intentions from Austria to harmonise the classification and labelling of:

- dibutyltin maleate; and
- dibutyltin oxide.

Meanwhile, Germany has submitted its CLH proposal for multi-walled carbon nanotubes (fibres fulfilling the WHO definition: diameter <3µm, fibre length > 5µm and aspect ratio ≥ 3:1, with a diameter > xxnm). Additional lower cut-off value for the diameter of the MWCNT will be clarified in the final CLH proposal. It is proposing a harmonised classification of carcinogenicity 1B and Stot RE 1.

In other news, the submission date for undecafluorohexanoic acid (PFHxA), its salts and related substances has been pushed back to 20 December (it was previously 27 September).

REACH Exposure Expert Group

The agency has created new web pages relating to the REACH Exposure Expert Group. The REEG brings together member state and Echa experts to discuss, collaborate and coordinate activities on use and exposure issues.

The group functions independently and supports authorities in their efforts to implement the integrated regulatory strategy. It also shares experiences and reflects on strategies, methods and tools for obtaining information related to use description, risk management measures and estimating exposure for hazardous substances.

Echa bank

Echa has changed is bank account and will update all REACH and biocides invoices with the new details from 1 July.

Any invoices issued prior to 1 July can be paid into either the old account or the new one.

Echa closure

The agency will be closed for a one-day holiday on Friday 21 June.

Further Information:

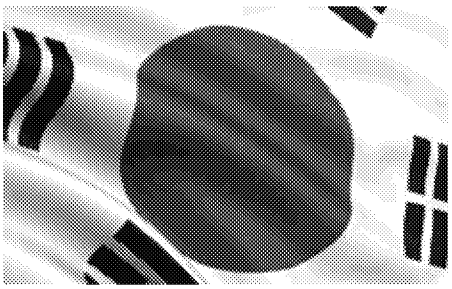
- Registry of intentions
- Undecafluorohexanoic acid
- REEG webpages

- Echa's bank details
- Echa's opening hours and holidays

South Korea adds pre-notification instructions just before deadline

Further details for UVCBs and substances lacking supplier information

13 June 2019 / K-REACH, South Korea, Substance registration



In last minute changes, South Korea's environment ministry has announced additional instructions for two special cases under K-REACH for the pre-notification of existing substances.

These were not fully covered in its previous pre-notification instructions.

Submissions are due to close on 30 June.

The additional details cover:

- UVCB substances (chemical substances of unknown or variable composition, complex reaction products and biological materials); and
- substances where overseas suppliers/manufacturers have failed to provide information due to CBI concerns.

In both cases, the MoE announcement instructs companies to submit pre-notifications by the 30 June deadline.

However, because companies may have incomplete information for their report, the ministry will accept what is currently available together with a plan to obtain the missing information.

The MoE will then allow companies to submit the complete pre-notification reports on these substances by 30 September.

The Korea Environment Corporation (Keco) – the agency under the MoE dealing with pre-notifications – told Chemical Watch that these cases had not been explicitly covered in the previous instructions and it is receiving enquiries from concerned companies requesting guidance.

Keco said it still expects all existing substances will be pre-notified by 30 June, taking into account partial reports in these two cases.

UVCB substances

For UVCBs – a particularly diverse collection of substances that, for instance, includes many petrochemical mixtures – submissions should, where possible, carry the following:

- basic information such as name, contents, classification and labelling;
- proof that the substances were manufactured/imported before 1991 (such as an import declaration or operational records); and
- a technical document on the manufacturing or synthesising process.

If any analysis data is available, such as chromatography that shows the contents of a mixture, that should be included.

If the UVCB substance is carcinogenic, mutagenic or reprotoxic (CMR) and subject to registration by 2021, then comprehensive information on classification and labelling will be required.

Only representatives (ORs) can report on behalf of overseas manufacturers.

Substances where suppliers fail to provide sufficient information

The MoE announcement also notes that pre-notification should still take place, where insufficient information has been made available from overseas suppliers/manufacturers.

This concerns, for example, cases where:

- substance information has not been disclosed due to CBI concerns; or
- where an only representative (OR) has not been appointed by the supplier.

It says that when companies have requested information from suppliers and they have not responded, or been unhelpful, they must still submit pre-notification with the information they have by 30 June.

This should include as much information as possible and include proof the company has made the necessary requests of the overseas supplier/manufacturer.

For both special cases, reports should be submitted to Keco by email rather than by the usual IT system.

Sunny Lee

Asia editor

Related Articles

- South Korea's MoE dismisses K-REACH pre-notification concerns
- South Korea's draft implementation rules arrive for updated K-REACH
- South Korea's MoE dismisses K-REACH pre-notification concerns

Further Information:

- MoE announcement (in Korean)

NGOs press TSCA advisory group to assess PV29 data adequacy

Controversy continues ahead of 18 June SACC meeting

13 June 2019 / Data, TSCA, United States

On the eve of the first TSCA risk evaluation peer review meeting, a coalition of NGOs has requested that an EPA advisory group address the adequacy of the data underlying preliminary findings for pigment violet 29.

The request came in a 23 May letter from five NGOs, posted to the public docket this week, and concerns next week's meeting of the Science Advisory Committee on Chemicals. The four-day public forum will see the body review the draft TSCA risk evaluation of PV29.

The evaluation – the first draft to be released by the EPA for the first ten substances subject to review under the reformed law – proposes to conclude that the substance does not pose an unreasonable risk to human health or the environment. But it has been mired in controversy since its November release, with critics taking issue with the quality and transparency of the data underlying it.

And now a coalition of NGOs – including the Natural Resources Defense Council (NRDC), Earthjustice and Safer Chemicals, Healthy Families (SCHF) – have asked the SACC to weigh in on the debate. The groups want it to determine whether the information is "sufficient to fully evaluate PV29 and support a finding of no unreasonable risk, and, if not, what additional information EPA should obtain prior to the finalisation of the risk evaluation".

There are "serious questions raised by the absence of credible data on multiple key health endpoints," the organisations wrote. They cite among their concerns the EPA's reliance on personal communications with a chemical manufacturer to derive workplace monitoring and environmental release information, as well as a screening study that they say cannot be used as the basis for a risk determination based on OECD and EPA risk assessment guidelines.

The groups also flagged up specific concerns around the "inconclusive" evidence supporting EPA's conclusion that PV29 has low solubility and bioaccumulation potential.

And they specifically ask whether several study summaries prepared by a chemical manufacturer "provide sufficient information concerning the underlying studies' methodology and data to evaluate reliability, accuracy of reporting and potential bias".

The SACC is set to convene for its meeting in Rosslyn, Virginia, beginning 18 June. The meeting had previously been scheduled to take place in January, but was cancelled due to the partial government shutdown. It was then further delayed to allow for reviews of the confidentiality claims of several of the studies relied on in the evaluation.

The peer review panel includes representatives from academia, industry, NGOs and government agencies.

Kelly Franklin

North America editor

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- EPA provides 'low hazard' preliminary TSCA conclusion on PV29
- EPA names first ten chemicals for new TSCA evaluations
- Data concerns fuel controversy over TSCA PV29 risk evaluation
- US government shutdown could delay TSCA risk evaluation
- TSCA data release does little to end PV29 controversy

Further Information:

- NGO comments
- PV29 docket
- SACC meeting
- Risk evaluation

Asean finds six non-compliant cosmetic products on sale

13 June 2019 / Brunei, Malaysia, Metals, Personal care, Philippines, Singapore

Three cosmetic products containing banned ingredients, and another three with mercury above the permitted level, were found on sale in the region covered by the Association of Southeast Asian Nations (Asean) by ongoing post-market surveillance programmes.

The products, which were tested by authorities in Brunei, Malaysia and Singapore, were found to be non-compliant with the technical standards set out by the Asean Cosmetic Directive (ACD).

The information was disseminated on the Philippines FDA website in Asean post-market alert (PMAS) reports. These were developed to share information on product safety among the ten member countries.

The products are:

- a face mask – containing arsenic;

- a whitening cream, a whitening cleanser and SPF 50 cream – containing mercury beyond 1 part per million (ppm); and
- two skincare creams – containing diphenhydramine.

Arsenic is not permitted in cosmetics under the ACD. The PMAS notice calls for a product recall.

Mercury is commonly used in skin lightening products because it hinders melanin production. Under the ACD it is permitted up to 1ppm. The PMAS does not specify the exact amount of mercury found but calls for 'withdrawal of products'.

Diphenhydramine is an antihistamine that is not allowed in cosmetic products under the Directive. The PMAS calls for 'cancellation of the notification', which involves, but is not limited to, recall and disposal of the affected product.

Ellen Tatham

Asia reporter

Related Articles

- Overview of Asean cosmetic regulations
- Overview of Asean cosmetic regulations

Further Information:

- PMAS - arsenic
- PMAS - mercury
- PMAS - diphenhydramine

Colombia bans production, sale, use of asbestos

Law will take effect in 2021

13 June 2019 / CMRs, Colombia

Colombia has banned the production, sale and use of asbestos.

The Latin American country's House of Representatives unanimously voted to ban the fibers, which are used as an insulator in many construction materials. The WHO has classified asbestos as carcinogenic in all forms, and said that more than 100,000 people die each year as a result of exposure.

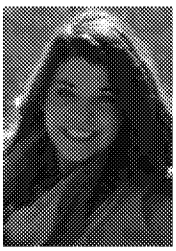
Colombia's ban, which also prohibits the mining and export of asbestos, will take effect in 2021.

According to newspaper Colombia Reports, the ban allows a five-year transition period for local companies that use asbestos in products.

Asbestos exposure has been highly political in Colombia, owing largely to the campaigning of journalist Ana Cecilia Niño, who believed that her lung cancer was due to exposure from an asbestos factory.

Ms Niño died in 2012. The law, passed on Tuesday, was named after her.

Meanwhile, Colombia is being informally assessed this year on whether it meets the qualifications for the OECD's scheme for mutual acceptance of data (MAD). The MAD scheme removes the need for duplicate testing for products which are marketed in several countries that accept MAD-approved testing and provides a "common basis for cooperation among national authorities and avoids creating non-tariff barriers to trade".



Ginger Hervey

UN/emerging markets reporter

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- Colombia to be informally assessed for OECD mutual data assurance scheme

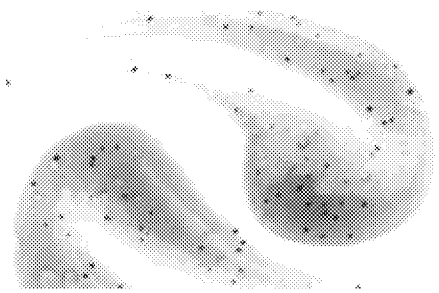
Further Information:

- House of Representatives tweet (in Spanish)
- WHO asbestos fact sheet
- Colombia Reports article

Italian cosmetic producer SMEs braced for proposed EU microplastics restriction

Country produces two-thirds of make up in Europe

13 June 2019 / Alternatives assessment & substitution, Italy, Microplastics, Personal care, REACH



Italian SMEs in the cosmetic industry have raised concerns about the potential economic impact of Echa's microplastics restriction proposal on their business.

The proposal aims to restrict intentionally added microplastics in all consumer and professional use products and comes after the European Commission requested it under the plastic strategy.

Italy has the fourth-largest sector in the EU, and employs 35,000 people – swelling to 200,000 when taking the entire supply chain into account – Italian trade body Cosmetica Italia told Chemical Watch.

And, the trade body said, Italy manufactures 65% of make up consumed in Europe. The costs of complying with the restriction could be very costly for hundreds of SMEs.

Meglena Mihova, of specialist management consultancy EPPA and vice-chair of the EU board of the American Chamber of Commerce, said these companies "very often produce one, two or three products, and fixed costs related to a restriction may impact them negatively".

She added that replacements take time and resources. And while "big companies can invest and maybe have a team of ten people working on research and development," the small ones often have only "ten people as employees as a whole".

A source close to the Italian authorities said the companies are "very worried". And they added that SMEs felt the agency's proposal had not taken them into consideration.

Echa told Chemical Watch that it did consider the impact on SMEs in its socio-economic analysis and made "extensive efforts to reach out to stakeholders during the preparation of the proposal and its submission".

It added that "all interested parties are invited to participate to the ongoing public consultation", which runs until 20 September.

Broad definition

Cosmetica Italia said Echa's definition of microplastics causes the most concern among Italian cosmetic producers.

Regulating a group of substances based on a 'broad' definition, does not "take into adequate consideration the principle that, despite all the plastics are polymers, not all polymers are plastics", it said.

Such a definition, the trade body said, is "not in line with REACH and with how industry believes the precautionary principle should be applied". A clear definition would be needed.

It suggests identifying a list of polymers subject to restriction through "relevant, feasible and applicable criteria, thus ensuring the necessary legal certainty of the economic operators and authorities".

Marko Susnik from trade body SMEUnited agreed, adding that defining the substance identity and determining the exact risk is "very challenging" and "causes a lot of uncertainty".

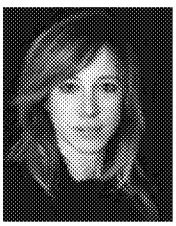
Echa's grouping approach, he said, "goes far beyond" what has been usual so far. His assumption is that "no authority would accept something so broad and diverse in a joint registration, nor for read-across-purposes. This means that we could become very inconsistent."

In some cases, he told Chemical Watch, enterprises would like to substitute their microplastic materials, but only if someone would "guarantee that their substitutes are out of the scope of the upcoming restriction".

Until then companies will not invest in alternatives, because it is "too risky", Mr Susnik said.

According to analysis by an international law firm – commissioned by Cefic – the proposal cannot be seen as appropriately meeting a legitimate objective under the REACH Regulation.

In a 6 May document seen by Chemical Watch, lawyers at the firm say this is because the agency has not identified a hazard or risk posed by the substances.



Caterina Tani

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- Echa begins consultation on microplastics restriction proposal
- Legal opinion casts doubt over proposed EU microplastics restriction

Expert Focus: Key REACH authorisation judgments offer lessons for companies

14 June 2019 / Europe, Legal cases, REACH

Marcus Navin-Jones, a Brussels-based law partner at Keller and Heckman, discusses two key EU General Court decisions on REACH authorisation and the questions raised for companies concerned about the time and cost implications.

When it rains it pours. Apparently the same is true for decisions on REACH authorisation. The start of this year saw a small wave of important decisions which began, arguably, in February when the European Commission rejected an application for authorisation for the first time.

Since then, the EU General Court has handed down two important judgments on REACH authorisation. The first came in March (Case T-837/16) in the Swedish/lead chromates case. The second came in April (Case T-108/17) in the ClientEarth/DEHP case.

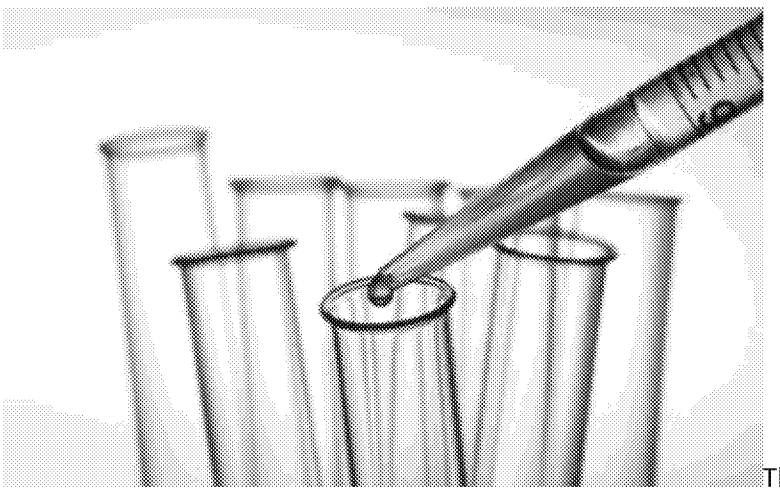
'Applicants for REACH authorisation should pay attention to these decisions'

Applicants for REACH authorisation should pay attention to these decisions. They contain valuable lessons on how to compile robust applications for authorisation. But they also raise bigger more fundamental questions.

Swedish/lead chromates case

Applicants for REACH authorisation continue to pore over the court judgment in the Swedish/lead chromates case. The Commission had granted a REACH only representative (OR) of a Canadian-based company REACH authorisation for certain uses of two lead chromates.

Sweden – with support from Denmark, Finland and the European Parliament – legally contested the Commission decision, arguing that the Commission had erred in law in granting the REACH authorisations. The court ultimately agreed with Sweden, annulled the Commission decision, and therefore essentially cancelled any permission for the OR to use the Annex XIV substances.



The Commission has since stated that it would appeal certain, but not all, aspects of the judgment – and the appeal case will no doubt shed further light and clarity on the REACH authorisation provisions.

ClientEarth/DEHP case

There are also important lessons for applicants for REACH authorisation to learn from the court judgment in the ClientEarth/DEHP case. In that case, the Commission had granted three waste recycling companies REACH authorisation for two uses relating to recycled PVC materials and DEHP. In August 2016, ClientEarth requested that the Commission conduct an internal review of its decision to grant REACH authorisations, which the Commission subsequently rejected.

ClientEarth then brought a legal action against the Commission, arguing that the Commission was wrong to reject its request for an internal review. More importantly, ClientEarth also argued that the Commission was wrong to grant the waste recycling companies REACH authorisation in the first place. The court rejected ClientEarth's arguments as

unfounded or inadmissible, and ultimately dismissed ClientEarth's case. The Commission's decision to grant REACH authorisation was therefore ultimately upheld and maintained by the court.

Outcome and reaction

The outcome of these two cases was therefore very different.

To put it crudely: in the Swedish case, the court essentially concluded that the REACH authorisation was illegal – and that the Commission had wrongly granted it.

In contrast, in the ClientEarth case, the court concluded, in essence, that the Commission had lawfully rejected the request for an internal review and that there were no legal grounds to question the Commission decision granting REACH authorisation.

The reaction to these judgments from industry has been varied. As the judgment in the Swedish/lead chromates case arguably makes it more difficult for applicants to obtain REACH authorisation, applicants have generally had more concerns regarding that judgment.

'There are valuable lessons to be learned from the court judgment in the ClientEarth/DEHP case'

But there are also valuable lessons to be learned from the court judgment in the ClientEarth/DEHP case – and applicants should take time to understand the core points underlying both these judgments.

Principal findings

One of the principal findings of the court in both judgments is that before granting a REACH authorisation, the Commission is legally required to conduct its own examination of the facts and circumstances surrounding the application for REACH authorisation. The Commission cannot simply defer to an Echa committee Opinion and refuse, or omit, to carry out its own full and complete examination.

It cannot merely rubber stamp or echo the view of an Echa committee. The Commission must "on its own motion" proactively establish what the facts and circumstances surrounding an application are, and establish whether the relevant legal conditions are satisfied.

This is an important point. It suggests that when the Commission assesses whether an application should be granted, its examination must be more autonomous, and more independent from Echa, than has been the case in the past.

It also suggests that the Commission's examination needs to go deeper and be more thorough than perhaps was previously the case.

Some question whether this seemingly new approach will mean that, in the future, the Commission might be more inclined to contradict or ignore Echa committee opinions. The Commission might, for example, reject applications for authorisation in the future, even after the Echa committees have concluded that the legal conditions have been met.

But, interestingly, the court has also clarified, particularly in the Swedish case, that although the Commission must conduct its own independent and thorough examination of the facts and circumstances, the Commission must – at the same time – take into account Echa committee opinions, and is able to derogate or disagree with an Echa scientific opinion only under certain conditions.

The court stated that, for example, where the Commission disagrees or derogates from an Echa committee opinion, the Commission must "give specific reasons for its assessment" and that the Commission's justification must "be of a scientific level at least equivalent to that of the opinion in question".

Concerns for REACH applicants

There is, therefore, some legal debate on whether the judgments, particularly in the Swedish case, ultimately tie the Commission's hands more tightly to an Echa committee opinion, and force the Commission to follow and adopt the same or a similar view of an Echa committee – or whether, alternatively, the Commission's independent and thorough examination will ultimately lead more divergences of opinion between the Commission and Echa.

But, regardless of this debate, the judgments are raising concerns for REACH applicants who have justified worries in investing significant time and money in compiling applications without at least having some idea of what the Commission – not Echa – will insist on seeing in an application, and without having at least some idea of if and when the Commission – not Echa – is likely to reject an application.

Whether the Commission could meet applicants in a pre-submission meeting as Echa generally does, or take other action to clarify the remit, scope and depth of their future examination would be of interest.

'Confirmation from the Commission that the judgment will have no impact on the costs charged to applicants, now or in the future, would also be helpful'

Confirmation from the Commission that the judgment will have no impact on the costs charged to applicants, now or in the future, would also be helpful.

Core finding

Another core finding from the court, which the ClientEarth case in particular highlights, is that the Commission cannot ignore or rectify deficiencies and flaws in applications for authorisation and then, despite these flaws, grant authorisations to applicants but shorten review periods, or narrow or change the authorised conditions of use.

One of the reasons for adopting REACH was to reverse the burden of proof. REACH authorisation, more than perhaps any other part of REACH including registration, seeks to achieve this objective.

In the Swedish case, the court stated unequivocally that an applicant was fully responsible for demonstrating that an alternative was not available to it and that the burden of proof "belongs to the applicant for authorisation". Where there are still "uncertainties" that an alternative is available to an applicant, the court concluded that it is the applicant who is essentially at fault and "the authorisation cannot be granted".

This again is a significant point. Industry has been calling upon EU authorities to address the significant, and arguably excessive, costs and time companies must invest in order to obtain a REACH authorisation.

Fears about time and costs

The judgments, particularly in the Swedish case, do nothing to alleviate the fears about the time and cost needed to get REACH authorisation – and arguably significantly exacerbates the problem.

This is rightly of most concern to SME companies who need REACH authorisation, but who simply do not have the time or financial resources that are apparently now needed to get it.

How does an applicant SME eradicate any possible uncertainties, in Echa's or the Commission's mind, that there is no alternative available to the SME – if EU member states, global chemical conglomerates, trade associations, NGOs and other stakeholders argue that an alternative is available to the SME – but, in reality, it is not?

At the same time, in principle there should be equal treatment between REACH applicants, and therefore SMEs should not, *per se*, be treated differently under the REACH authorisation provisions than applicants.

Industry reaction

How industry reacts to this underlying problem is still unclear. SMEs could, for example, try to push other companies in their supply chain to compile REACH authorisations – but those SMEs would then still presumably need to share in the costs and may have less control over them.

'Companies may be ultimately forced to conclude that REACH authorisation costs, coupled with market forces, are simply too much to bear'

Or, companies may be ultimately forced to conclude that REACH authorisation costs, coupled with market forces, are simply too much to bear – and take the more drastic and irrevocable decision to close business altogether – as was the case for one of the applicants in the ClientEarth case.

To a certain degree, the judgment in the ClientEarth case, handed down in April, has already been overtaken by events in reality.

Only one of the original three recycling companies has persisted in pursuing REACH authorisation. The Waste Framework Regulation has been updated. The adequate control route now appears well able to support the grant of a REACH authorisation *vis-à-vis* repro-toxicity aspects. And the basis for the Annex XIV inclusion looks set to be updated to include the endocrine-disrupting properties justification.

Far-reaching implications

But the judgment in the ClientEarth case has far-reaching implications, particularly for recyclers. Where a recycler believes that an Annex XIV substance is merely an unintended ingredient in a mixture (similar to an impurity in a substance) which is merely present in a recycled material – but not considered, by the recycler, as "used" – the court has now essentially held that there is still "use" of that Annex XIV substance where it has a function in a mixture (such as reducing the amount of plasticisers within it).

This opens up other questions for recyclers. For example, when (if ever) is the presence of an Annex XIV substance in a recovered or recycled product so low that it cannot be regarded as having a function within it? And when (if ever) do the performance characteristics of an Annex XIV substance deteriorate so much over time that the Annex XIV substance cannot be regarded as having a function any longer?

The ClientEarth judgment also highlighted another important issue – namely how REACH applicants for authorisation should define "use". How broadly applicants should define "use" is of critical importance – in many ways the starting

point – for applicants, dictating not merely whether REACH authorisation is needed at all, but also how many REACH authorisations are needed in any one particular area.

In the ClientEarth judgment, the court agreed that the concept of "use" was indeed important, particularly in assessing whether the legal conditions for granting an authorisation were satisfied including, therefore, in assessing alternatives and their availability.

Uncomfortable truths

One of the perhaps uncomfortable truths that the ClientEarth judgment exposed was the apparent conflict between the drive towards creating a circular economy and the desire, from some quarters, for a completely toxic-free environment.

Will the drive towards banning the sale and use of Annex XIV substances impede any or all recovery and recycling, or perhaps mean significant amounts of Annex XIV substances ultimately end up in a limited and concentrated number of products?

Should recyclers really be considered as "using" unwanted ingredients in their products? And should recycling be more considered *vis-à-vis*, for example, Article 58(2) REACH carve-outs?

The circular economy cannot be adequately created if practical – but also legal – solutions are not found. Applicants for REACH authorisation – but also regulators – will therefore need to consider the full impact of these judgments, and what lessons can be learned.

The views in this article are those of the expert author and are not necessarily shared by Chemical Watch.

Marcus Navin-Jones

Partner Keller & Heckman

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- Commission to appeal EU court judgment on lead chromate authorisation
- ClientEarth loses landmark case on recycled PVC authorisation
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Further Information:

- Case T-837/16
- Case T-108/17

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